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Docket No.: 0020-5493PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yoshiko MINAKUCHI et al.

Application No.: 10/583,277

Confirmation No.:

Filed: June 16, 2006

Art Unit: N/A

For: NOVEL METHOD OF NUCLEIC ACID
TRANSFER

Examiner: Not Yet Assigned

L E T T E R

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on June 16, 2006, attached hereto is an English translation of the International Preliminary Examination Report on Patentability (Form PCT/IB/338 and 373) and of the Written Opinion of the International Searching Authority (Form PCT/ISA/237) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: October 17, 2006

Respectfully submitted,

By Mark J. Nuell
Mark J. Nuell

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Attachment(s)

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

ISOBE, Yutaka
Intellectual Property (Kasugade)
Dainippon Sumitomo Pharma Co., Ltd.
1-98, Kasugadenaka 3-chome
Konohana-ku, Osaka-shi
Osaka 5540022
JAPON



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|---|
| Date of mailing (day/month/year) 31 August 2006 (31.08.2006) |
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|--|
| Applicant's or agent's file reference 533764 <i>日本(カナダ)輸入登録</i> |
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| International application No. PCT/JP2004/019160 |
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| Applicant Dainippon Sumitomo Pharma Co., Ltd. et al |
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IMPORTANT NOTIFICATION**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| | | | |
|--|--|--|------------------|
| Applicant's or agent's file reference 533764 | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2004/019160 | International filing date (<i>day/month/year</i>) 15 December 2004 (15.12.2004) | Priority date (<i>day/month/year</i>) 19 December 2003 (19.12.2003) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant Dainippon Sumitomo Pharma Co., Ltd. | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
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| | Date of issuance of this report 22 August 2006 (22.08.2006) |
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Authorized officer Masashi Honda e-mail: pt08@wipo.int |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

| | | |
|---|---|---|
| | | Date of mailing (day/month/year) |
| Applicant's or agent's file reference 533764 | | FOR FURTHER ACTION See paragraph 2 below |
| International application No. PCT/JP2004/019160 | International filing date (day/month/year) 15.12.2004 | Priority date (day/month/year) 19.12.2003 |
| International Patent Classification (IPC) or both national classification and IPC | | |
| Applicant Dainippon Sumitomo Pharma Co., Ltd. | | |

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|--|--------------------|
| Name and mailing address of the ISA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/019160

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019160

Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
 paid additional fees
 paid additional fees under protest
 not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
 complied with
 not complied with for the following reasons:

The “special technical feature” of Claim 1 relates to a method of nucleic acid transfer using a highly concentrated metal salt solution, while the “special technical feature” of part of Claims 14-21 relates to a nucleic acid transfer agent containing a solid metal salt as a component thereof.

Since there is no technical relationship among these inventions involving one or more of the same or corresponding technical features, they do not appear to be so linked as to form a single general inventive concept.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

all parts
 the parts relating to claims Nos. parts of 1-13 and 14-21

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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|-------------------------------|-------------------|
| International application No. | PCT/JP2004/019160 |
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| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
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1. Statement

| | | | |
|-------------------------------|--------|-------|-----|
| Novelty (N) | Claims | 1-13 | YES |
| | Claims | 14-21 | NO |
| Inventive step (IS) | Claims | 1-13 | YES |
| | Claims | 14-21 | NO |
| Industrial applicability (IA) | Claims | 1-21 | YES |
| | Claims | | NO |

2. Citations and explanations:

Document 1: JP 2002-325572 A (President of Osaka University), 12 November 2002
 Document 2: JP 2001-335512 A (Yamanouchi Pharmaceutical Co., Ltd.), 04 December 2001
 Document 3: JP 01-157388 A (Mitsubishi Heavy Industries, Ltd.), 20 June 1989
 Document 4: JP 04-091783 A (Toyobo Co., Ltd.), 25 March 1992
 Document 5: JP 2003-274950 A (President of Osaka University), 30 September 2003
 Document 6: WO 00/73414 A1 (Pinar BULUT), 07 December 2000
 Document 7: WO 01/97857 A1 (Sumitomo Pharmaceuticals Co., Ltd.), 27 December 2001
 Document 8: Biochem. Biophys. Res. Commun., 2001, Vol. 289, No. 5, pp. 1075-81
 Document 9: Jikken Igaku, 1999, Vol. 17, No. 17, pp. 2288-91

Claims 14-21

The inventions described in Claims 14-21 do not appear to be novel based on documents 3 and 5 cited in the ISR.

Document 3 describes using a 1 M calcium chloride solution prior to transforming *E. coli* with a nucleic acid.

Document 5 describes adding an 0.2 M calcium chloride solution to the culture liquid when transforming cells with bio-beads comprising exogenous genetic material.

The calcium chloride solutions described in documents 3 and 5 are used when transforming cells using nucleic acids, and appear to be identical to the high-concentration metal salt solution of the invention of this application.

The inventions described in Claims 14-15 and 18-21 do not appear to be novel based on documents 1-2 and 4 cited in the ISR.

Documents 1-2 describe using calcium chloride when transforming cells using an exogenous gene.

Document 4 describes using a calcium chloride solution prior to transforming *E. coli* with a nucleic acid.

The calcium chloride solutions described in documents 1-2 and 4 are used when transforming cells using nucleic acids, and appear to be identical to the high-concentration metal salt solution of the invention of this application.

(Continued in Supplemental Box)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/019160

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Claims 14-21

The inventions described in Claims 14-21 do not appear to involve an inventive step over documents 1-5 cited in the ISR.

It would be easy for a person skilled in the art to adjust the concentrations of the calcium chloride solutions described in documents 1-5 in Claims 14-21.

Claims 1-13

The inventions described in Claims 1-13 are not described in any of documents 1-8 cited in the ISR, and appear to be novel and to involve an inventive step.

Documents 1-8 do not describe a nucleic acid transfer method in which a high-concentration metal salt solution is brought into contact with a medium after a nucleic acid and cells have been brought into contact with each other in that medium, nor could this be easily arrived at by a person skilled in the art.